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Attorneys for Plaintiff
PharmaTech Solutions, Inc.

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

PHARMATECH SOLUTIONS, INC.

Plaintiff,

vs.

SHASTA TECHNOLOGIES, LLC,

Defendant.

Case No.: 5:14-cv-03682 BLF

DECLARATION OF MARK E. DUVAL, ESQ. IN SUPPORT OF OPPOSITION TO MOTION TO DISMISS PURSUANT TO FRCP 12(b)(1) and 12(b)(6); AND

Date: April 16, 2015
Time: 9:00 a.m.
Place: Courtroom 3, 5th FL

DECLARATION OF Mark E. DuVal, ESQ.

I, Mark E. DuVal , declare:

1. I am an attorney duly authorized to appear before all courts in the state of Minnesota. I have personal knowledge of all facts as stated in this Declaration. If called to testify, I could competently testify to the following.

2. I am the owner, President and CEO of DuVal & Associates, P.A. located at 1820 Medical Arts Building, 825 Nicollet Mall, Minneapolis, Minnesota. Our firm, and myself, specialize in providing legal and regulatory counsel to medical device, pharmaceutical, dietary, and food firms. We have worked with over 600 regulated firms. As such, I regularly advise clients in all areas of law and regulation administered and enforced by the United States Food and Drug Administration (hereafter "FDA"). I consider myself to be an expert in this field. (A true and accurate copy of my professional resume is attached hereto as Exhibit A.)

3. I have represented both Shasta Technologies, LLC and PharmaTech Solutions, Inc. with respect to the issues arising out of the FDA's inspection of Shasta in December 2014. It is my understanding in interfacing with the FDA that, in December 2014, the FDA conducted a surprise inspection of Shasta as the "manufacturer" of record for their cleared device, the GenStrip™ glucose test strips. The place of inspection, however, was no more than the home of Calvin A. Knickerbocker, III, the son of Calvin A. Knickerbocker, Jr., Shasta's managing member.

4. FDA knew that Shasta's contract manufacturer, Conductive Technologies, Inc. ("CTI"), was in Pennsylvania, but from a regulatory perspective considered Shasta the "specification developer" and "manufacturer" of the device, as registered by Shasta with the FDA, and as defined under the Food, Drug & Cosmetic Act (the "Act"). FDA expressed concern that Shasta did not seem to have any quality controls, or even a quality control program, in place to satisfy compliance with FDA's regulations

pertaining to the safe manufacture, distribution, and sale of the GenStrip, a Class II medical device. GenStrip was, to the best of my knowledge and understanding (coming from Calvin Knickerbocker, Jr.) developed by Shasta, contract manufactured by CTI and distributed by PharmaTech, Shasta's distributor. FDA made observations in its inspection of Shasta that Shasta had failed to put together and exercise an appropriate quality system in which Shasta could demonstrate its control over the design history file and technology transfer process and the process of manufacturing and releasing product. In conversations with the FDA, it became clear that FDA had little confidence in Shasta's capabilities and ability to demonstrate it could create and manage a quality system. We defended Shasta's position to the best of our ability with the Agency. The FDA eventually published a very serious warning letter to Shasta demanding that it respond to the numerous violations and items of non-compliance discovered during the December inspection.

5. In the interim, in an effort to prevent the FDA from forcing a physical recall of the GenStrip from the market and/or taking other serious regulatory action (seizure of product or enjoining its sale), I first recommended to Mr. Knickerbocker, III., and later to Calvin Knickerbocker, Jr. and Keith Berman, the CEO of PharmaTech, that they should consider making PharmaTech the "manufacturer" and "specification developer" of the GenStrip since the FDA, again, seemed to have little confidence in Shasta. We were concerned that Shasta would not get out from under this inspection and warning letter unless things changed rather dramatically. We felt FDA would have more confidence and would be less likely to take precipitous regulatory action, if PharmaTech became the "manufacturer" and "specification developer" for the product. To do that PharmaTech would have to develop and implement the requisite quality control program and respond to other observations (deficiencies) made in FDA's Form 483 observations and the warning letter.

6. While the GenStrip is actually physically made by CTI, located in York, Pennsylvania, CTI is not the "manufacturer" of the GenStrip for FDA registration

purposes. It is a contract manufacturer whose activities are directed by the actual manufacturer of record to manufacture product meeting specifications and the FDA quality system regulations. In furtherance of that effort and to inspire renewed confidence in the FDA, Mr. Berman agreed to become the "manufacturer" of record and "specification developer" and made the decision to open an office at CTI's location in York after receipt of the FDA's warning letter to Shasta. Thereafter, PharmaTech and CTI worked together to develop a quality control program and the proper manufacturer registration documents.

7. Mr. Berman has represented to me that the establishment of PharmaTech's office in York, Pennsylvania is where the quality control program, and other FDA documents are located, that the office is there to: (i) provide PharmaTech with a base from which to ensure compliance with the quality control regimen, and any further FDA plant inspections; and (ii) to make any necessary decisions with respect to the manufacturing, distribution, and sale of the GenStrip so PharmaTech can maintain compliance with the FDA's regulations regarding the same. To the best of my knowledge and belief, PharmaTech manages the manufacturing of GenStrip in York, PA, accepts delivery of finished product manufactured under contract by CTI in York, PA, and all shipments for this product accepted by PharmaTech are done in and from Pennsylvania.

8. During the period of time that PharmaTech was a Good Manufacturing Practices (GMP) expert working for us, Jeff Zumhofe, to inspect both CTI and PharmaTech to insure the quality plan and prepare both companies for another FDA inspection. PharmaTech was inspected by our expert in the Pennsylvania facility, and also in California, where PharmaTech maintains a customer complaint call center. The quality plan seems to have been accepted by the FDA. Mr. Zumhofe's first report was issued during the second week of August 2014. The FDA's inspection of PharmaTech's overarching quality system did not receive any 483 observations (deficiencies) during a December 2014 inspection.

I declare under the penalty of perjury under the laws of the state of California that the forgoing is true and correct. Executed this 27th day of March, 2015 at Minneapolis, Minnesota.

Mark E. DuVal

Mark E. DuVal, J.D., FRAPS
DuVal & Associates, P.A.
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Highly skilled FDA lawyer with extensive regulatory and general counsel experience in the medical device, pharmaceutical, biotech and dietary supplement industries.

PROFESSIONAL EXPERIENCE

DuVal & Associates, P.A., Minneapolis, Minnesota **June 2005 to present**
President

- Firm has provide legal/regulatory counseling to over 500 medical device, pharmaceutical, dietary supplement and food firms.
- Counsels both mature and venture-backed pharmaceutical, medical device, biotech, food and nutritional supplement companies in the United States and Europe.
- Works extensively with combination products.
- Regularly advises clients in all areas of FDA law and regulation, from product clearances/approvals, panel meetings, development, clinical trials, inspections and recalls to reimbursement and compliance issues and post-marketing responsibilities.
- Specializes in counseling medical device and pharmaceutical companies in the development and implementation of strategic and tactical sales and marketing plans that are appropriately aggressive, yet compliant.
- Continued private practice providing FDA, Anti-kickback statute and False Claims Act legal advice to medical device, pharmaceutical and biotech as well as companies selling dietary supplements and medical and functional foods.
- Frequently travels to FDA with medical device clients to negotiate clinical trial (Investigational Device Exemption) approvals, 510(k) clearances, de novo and PMA approvals, reclassifications and FDA panel meetings, responding to FDA warning letters, etc.
- Drafted and sought industry input on two surveys addressing CDRH in 2012 through Medtech Resource Alliance.
- Filed Citizen Petition with FDA challenging FDA's administration of the 510(k) program on January 2, 2013.

Klepinski & DuVal, P.A., Minneapolis, Minnesota **October 2002-May 2005**
Vice President and Managing Partner

Started law firm to provide FDA, Anti-kickback statute and False Claims Act legal advice to pharmaceutical, biotech, medical device firms as well as companies selling dietary supplements and medical and functional foods.

Medtronic, Inc., Minneapolis, Minnesota **May 2001-Sept. 2002**

Senior Legal Counsel, Corporate Regulatory Compliance Services

Corporate-wide expert on FDA, Anti-kickback, False Claims Act and Antitrust and medical device and pharmaceutical issues. Reported to Vice President, Corporate Regulatory Compliance Services. Primary Regulatory Legal Counsel to Neurological, Drug Delivery, Diabetes, Vascular and Spinal businesses; back-up to Cardiac Rhythm Management, heart valves, cardiac surgery, perfusion systems, spinal, ear nose and throat businesses. Responsible for FDA and antitrust due diligence issues in acquisitions and other business combinations. .

- Hired to be "a lawyer to the lawyers" and their business teams. Provided FDA regulatory advice on device and drug approvals, clinical trials, GMPs/QSRs, post-marketing, advertising and promotion, inspections, export/import, etc. Specialist in strategic regulatory and intellectual property planning, combination product/drug delivery issues (drug/device and biologic/device) and in FDA/FTC advertising and promotion regulations.

- Provided Anti-kickback and False Claims Act advice to business teams and their lawyers.

- Developed compliance programs for business units. Emphasis on training, education and drafting corporate legal guidance for antitrust and FDA compliance.

- Also provided counsel on antitrust, distribution, channel management strategies, pricing, Robinson-Patman, Hart Scott Rodino, etc.

- Counsel for Medtronic trade association and standard-setting participation (Noerr-Pennington antitrust immunity).

- Assisted in due diligence in acquisitions, provide transactional and antitrust advice on business development agreements especially with pharmaceutical and drug delivery companies.

3M Company, St. Paul, Minnesota **November 2000 – May 2001**
Senior Counsel, 3M Pharmaceuticals Division and Corporate Services
Reported to Staff Vice President and Deputy General Counsel.

- Resumed role as US and Global Senior Counsel to 3M Pharmaceuticals (see below).

- Assigned as lawyer to newly formed 3M Intellectual Property Company to assist business team in finding a commercial "home" for 3M's portfolio of under-utilized or underutilized patented 3M technologies.

- Assigned as lawyer to 3M Global Trading (export and import) corporate business unit.

3M Company, Loughborough, United Kingdom
Senior Counsel, Europe, 3M Health Care, Ltd. **April 2000 – Nov. 2000**

Worked in Pan-European assignment as general counsel for 3M Pharmaceuticals. Reported to Staff Vice President and Deputy General Counsel. Reported (dotted line) to European Vice President and General Counsel and Managing Director, 3M Health Care, Ltd. Sat on European Pharmaceutical Operating Committee.

- International responsibilities for major transactional, e-business, competitive and strategic regulatory work.

- Experience with health care regulations (pharmaceuticals and medical devices) and legislation and regulatory agencies in the EU.

- Worked on distribution strategies, parallel imports and pricing corridor strategies. Experience in contracting with and terminating licensees, distributors and co-promotion partners (litigation experience as well). Provided counseling on EC competition law issues.

- Conducted education/training on topics like strategic regulatory and intellectual property planning, contracts, EC Competition Law Directive, EC Product Liability Directive, EC Medicines Advertising Directive, EC Data Exclusivity Act. Instituted global compliance programs.

3M Company, St. Paul, Minnesota **1986-2000**
Senior Counsel, 3M Pharmaceuticals and Drug Delivery Systems Divisions

Acted in capacity of general counsel for 3M's pharmaceutical and drug delivery businesses with over one billion dollars in worldwide sales. Reported to Staff Vice President and Deputy General Counsel, and sat on 3M Pharmaceuticals' Global Management Committee, North American Division Operating Committee, Global Compliance Oversight Committee, Global e-Business Committee, and Pricing Committee, acting as general counsel for division.

- Lead attorney for pharmaceutical legal staff in and outside of U.S. (U.K., France, Germany, Italy, Canada, Australia and Latin America.) Legal counsel to division management committees. Managed many complex and high profile business/legal/political matters for business management. Responsible for establishing budget for outside counsel (antitrust, regulatory, commercial and product liability litigation).

- Expertise in pharmaceutical and medical device regulation, especially combination/drug delivery products. Established compliance programs for antitrust, EC competition, FDA regulations, anti-kickback and related laws. Instituted divisional education programs on wide variety of topics, including but not limited to, contracts, distribution law, FDA advertising and promotion law, Lanham Act, "Writing Smart", antitrust, FDA regulations (drug/device approvals, clinical trials, post-marketing issues, regulatory inspections, etc.) Recognized industry expert and frequent speaker on FDA advertising and promotional issues and in dealing with FDA generally.

- Created and co-chaired divisional Competitive Initiatives Committee whose responsibility was to conduct strategic regulatory and intellectual property

planning and to track competitive activity and devise strategies to advantage client and/or disadvantage competitors.

- Expertise in devising distribution channels and sales and marketing strategies in complex, highly-regulated environment (FDA and European advertising and promotional regulations, anti-kickback, antitrust, EC Competition Law Directive (including parallel imports analysis, etc.)

- Demonstrated skills in strategic transactional counseling and hands-on contract drafting and negotiating supply, vendor, distribution, co-promotion, co-marketing and co-development agreements, as well as in acquisitions, divestitures and joint ventures. Negotiated with some of largest, most sophisticated pharmaceutical and drug delivery companies in the world.

- Managed product liability and commercial litigation and assisted IP counsel on intellectual property litigation. Significant experience handling major national product liability crisis with international major media network coverage (PrimeTime Live, 20/20, Good Morning America, etc) congressional hearings and intense regulatory scrutiny.

- Formerly office expert at 3M in bankruptcy, workouts and secured transactions; developed educational presentations and instructional memoranda on bankruptcy, U.S. Intellectual Property Licenses in Bankruptcy Act, lender liability, fraudulent conveyances, bulk transfers, guarantees, letters of credit and Article 9 issues. Created "model" documents for corporate acquisition and credit groups, i.e., security agreements, promissory notes, guarantees, subordination and inter-creditor agreements.

Larkin, Hoffman, Daly & Lindgren, Ltd., Associate Mpls., MN **2/83-6/83, 6/84-7/86**

Business litigation and counseling specializing in business fraud, RICO, securities, board of directors and shareholder disputes (D&O liability, minority "squeeze-outs," mandatory buy-outs, etc.), bankruptcy and UCC litigation (Art. 2, 5, 6 and 9).

Law Clerk to Honorable Justice John J. Todd, Minnesota Supreme Court **6/83 – 6/84**

EDUCATION

- William Mitchell College of Law (WMCL) - J.D. Cum Laude (1983)
  - Executive Editor, WMCL Law Review
  - WMCL Student Bar Association Representative
- St. Cloud State University (SCSU) - Bachelor of Science, Public Administration - Cum Laude (1979)
  - President, Minnesota State University Student Association
  - President, SCSU Student Senate

PROFESSIONAL MEMBERSHIPS

- 2012 RAPS Fellow, Regulatory Affairs Professionals Society.
- Co-Founder and Board of Directors, Minnesota Medical Device Alliance (January 2010-present)
- Board of Directors, Food and Drug Law Institute (FDLI), Washington, D.C. (2005-2009)
- Advisory Board Member, St. Cloud State University Masters of Science in Regulatory Affairs and Services degree program (2007-present)
- Program Committee Medical Devices, Food and Drug Law Institute (FDLI) (2000-present
- Member, LifeScience Alley (Minnesota) (formerly Medical Alley)
- Founding Member Medtech Resource Alliance (MRA)
- Programming Committee – International Business Forum (IBF)/LifeScience Alley Annual MedTech Conference
- Former Board of Advisors, International Business Forum (IBF)/LifeScience Alley Annual MedTech Conference (2007-10)
- Editorial Advisory Board, Publication "Medical Device Compliance" (2007-present)
- Editorial Board, Publication "FDA News" (2010-present)
- Member, Regulatory Affairs Professionals Society (RAPS) Member
- Board Member, Minnesota BioBusiness Alliance (2005 –present)
- Member, Governor Tim Pawlenty's Minnesota Biosciences Council (2003-2004)
- Member, Mayor Randy Kelly's, City of St. Paul, Biotech Advisory Committee (2002-03)
- Member, Pharmaceutical Research Manufacturer's Association (PhRMA) Law Section (1987-2001)
- Member, PhRMA Law Section, Executive Committee (1987-2001)
- Member, AdvaMed, Combination Products Committee (2000)
- Member, Minnesota State and Hennepin Country Bar Associations
- Former Chair, Minn. State Bar Assoc.--Food, Drug and Medical Device Law Section (2003)
- Member, Minn. State Bar Assoc.--Food, Drug and Medical Device Section (1990 to present)
- Former member of Rand Corporation group which studied pharmaceutical and medical device product liability

OTHER

- Board Member, P3 Scientific, Inc. (2005-2007)
- Former Advisory Board, HCPro's monthly publication, "Briefings on Drug Safety"

References available upon request.

SPEAKING ENGAGEMENTS

- Speaker, UGA Medical Device Regulations Conference, "The Pre-Submission Meeting: Friend or Foe?" Athens, GA, (November 5, 2014).
- Speaker, Q1 Productions: Medical Device Regulatory Clearance and Approval Conference, "Encouraging Communications & Transparency Between Industry and Regulators," Arlington, VA (November 4, 2014).
- Speaker, Life Science Alley, "Smoldering Submission Issues: 510(k), PMA & DeNovo," Minneapolis, MN (October 28, 2014).
- Speaker, DuVal EDU Regulatory Training Webinar, "Marketing your Medical Device in the New FDA/OIG Enforcement Environment: Part 4 of 4 (October 7, 2014).
- Speaker, RAPS Conference, "Meeting Challenges in FDA 510(k) Review," Austin, TX (September 30, 2014).
- Speaker, DuVal EDU Regulatory Training Webinar, "Marketing your Medical Device in the New FDA/OIG Enforcement Environment: Part 3 of 4 (September 10, 2014).
- Speaker, RAPS Webinar, "FDA Hot Topics: Update on Medical Device Guidances," (August 27, 2014).
- Speaker, DuVal EDU Regulatory Training Webinar, "Marketing your Medical Device in the New FDA/OIG Enforcement Environment: Part 2 of 4 (July 8, 2014).
- Speaker, DuVal EDU Regulatory Training Webinar, "Marketing your Medical Device in the New FDA/OIG Enforcement Environment: Part 1 of 4 (June 10, 2014).
- Speaker and Panelist, BioEnterprise: Navigating the FDA: Medical Devices Event, "FDA Device Clearance Process," Cleveland, OH (May 14, 2014).
- Speaker, DuVal EDU Regulatory Training, "Helping FDA Clear Your 510(k): Understanding FDA's Wants & Needs," Boston, MA (April 3, 2014).
- Panelist, Orthopedics Companies Risk Management Panel Discussion, New Orleans, LA (March 12, 2014).
- Speaker, MD&M, "Navigating Through PMA and 510(k) Submission Processes," Anaheim, CA (February 11, 2014).
- Speaker, RAPS Atlanta Chapter, "Like Drinking Out Of A Fire Hose: Keeping Up With FDA's 510(k) FDASIA-Related Changes," Atlanta, GA (February 6, 2014).

- Speaker, Q1 Productions, "Navigating the Changing Regulatory Landscape by Forecasting Effects of New FDA Guidances," Raleigh, Durham, NC (January 30, 2014).

- Speaker, DuValEDU Regulatory Training, "Helping FDA Clear Your 510(k): Understanding FDA's Wants & Needs," Irvine, CA (January 17, 2014).

- Speaker & Panelist , Q1 3rd Annual Medical Device Regulatory Clearance & Approval, "Moving in the Right Direction: Regulatory Progress in Device Clearance & Approval" and "Panel Discussion: Balancing the level of detail with the continual increase of data requirements," Alexandria, VA (October 28th and 29th, 2013).

- Speaker, Life Science Alley, "Changing the Trajectory of the 510(k) Program," Minneapolis, MN (October 25, 2013).

- Speaker, BioHouston CEO Summit, "Current Regulatory Issues Effecting Device Sector," Austin, TX (October 24, 2013).

- Speaker, EXPO 2013 MichBio Expo & Conference, "Regulatory Pains," Kalamzoo, MI (October 16, 2013).

- Panelist, NASS, "Panel Roundtable Discussion with CEOs," New Orleans, LA (October 11, 2013).

- Speaker, RAPS Minneapolis Chapter, "Changing the Trajectory of the 510(k) Program," Minneapolis, MN (August 28, 2013).

- Speaker, OCRA – FDA Conference, Irvine, CA (June 12, 2013)

- Speaker, Xavier University – MedCon 2013, "510(k) Delays: Is it FDA or Quality?" Cincinnati, OH (May 2, 2013).

- Speaker, 10x Medical Device Conference, "Implications of FDA's Ill-Conceived 510(k) Draft Guidance," Minneapolis, MN (April 29, 2013).

- Speaker, Bowman & Brooke Medical Device & Pharmaceutical Hot Topics, "FDA's Attack on 510(k) Device Use and Labeling: Interpreting General vs. Specific Use," Minneapolis, MN (April 18, 2013).

- Speaker, Compliance OnLine/Metric Stream, "Clear as Mud: Obtaining your 510(k) with Today's FDA," San Diego, CA (March 14th and 15th, 2013).

- Speaker, Life Science Alley, "De Novo Program," Minneapolis, MN (February 20, 2013).

- Speaker, MD&M Conference, "Strategies for the 510(k) pathway: Submission & approval," Anaheim, CA (February 12, 2013).

- Speaker, RAPS, "Obtaining and Marketing 510(k) with Today's Tougher FDA Review Process," Atlanta,GA (January 24, 2013).

- Speaker & Panelist, 2nd Annual Medical Device Regulatory Clearance & Approval, "Update on 510(k) Changes: Timeline for Implementation and Assessment of Effects on Industry," and panel discussion: "Analyzing Industry's Debate Over Draft Guidances," Baltimore, MD (October 15-16, 2012).

- Speaker, ANYA NVCA CEO Meeting, Minneapolis, MN (September 11, 2012).

- Speaker, Metric Stream/Compliance Online, "Obtaining and Marketing Your 510(k) with Today's FDA, a 510(k) Workshop," San Francisco, CA (June 28-29, 2012).

- Panelist, 2012 Health Law Institute, MN CLE, "510(k) Program," Minneapolis, MN (June 7 & 8, 2012).

- Panelist, MedCon 2012, Medical Device Conference FDA & Xavier University, "510(k) An Industry Perspective," Cincinnati, Ohio (May 1-4, 2012).

- Speaker, Minnesota State Bar Association & LifeScience Alley, "Medical Device Guidance Workshop," Minneapolis, Minnesota, (March 29, 2012).

- Speaker, LifeScience Alley, "Obtaining and Marketing Your 510(k) with Today's FDA, a 510(k) Workshop," St. Louis Park, Minnesota, (March 1, 2012).

- Speaker, MetricStream/Compliance Online, "Clear as Mud: Obtaining and Marketing Your 510(k) With Today's FDA," Salt Lake City, Utah (January 27, 2012).

- Speaker, Thompson Publishing Group, "Off Label Promotion: Lessons Learned from Recent Enforcement Activity," Live National Webinar, United States (December 07, 2011).

- Speaker, Austrian CEO MedTech Forum, "Presentation & Workshop on Regulatory 510(k) & PMA," Minneapolis, Minnesota, (December 5, 2011).

- Instructor, St. Cloud State University, Master of Science in Regulatory Affairs and Services, "Combination Products RAS 621 Class," 3 credits. (November 14, 2011).

- Panelist, Mid-America Health Care Venture Forum, Louisville, Kentucky (November 8, 2011).

- Speaker, MetricStream/Compliance Online, "Clear as Mud: Obtaining and Marketing Your 510(k) With Today's FDA," Boston, Massachusetts (October 21, 2011).

- Speaker, MetricStream/Compliance Online, "Advertising and Promoting FDA Regulated Products--Is Your House In Order?" Live National Webinar, United States (October 19, 2011).

- Speaker, Swiss MedTech, Washington, D.C. (September 26, 2011).
- Moderator, LifeScience Alley, "Advertising and Promoting FDA Regulated Products-An Update on Prosecution and Trends," New Brighton, Minnesota (June 22, 2011).
- Speaker, LifeScience Alley, "Obtaining and Marketing Your 510(k) with Today's FDA, a 510(k) Workshop," St. Louis Park, Minnesota, (June 16, 2011).
- Speaker, MedCon 2011 Medical Device Conference, "Physician Initiated Trials and 510(k) Clinical Data," Cincinnati, OH, (May 3, 2011).
- Speaker, OsloMedTech, "A Political Update on the 510(k) program: an Alice in Wonderland Experience" and "Clear as Mud Obtaining a 510(k): A Perspective From Lake Wobegon," Oslo, Norway (April 4, 2011).
- Panelist, BioHouston, "FDA, CMS and the Current Regulatory environment," Austin, TX (February 24, 2011).
- Speaker, MetricStream/Compliance Online, "Clear as Mud: Obtaining and Marketing Your 510(k) With Today's FDA," San Francisco, CA (January 21, 2011).
- Speaker, MetricStream/Compliance Online, "Clear as Mud: Obtaining and Marketing Your 510(k) With Today's FDA," Irvine, CA (January 20, 2011).
- Speaker, Minnesota State Bar Association & LifeScience Alley, "Compliance: Don't Be Too Late Getting Your House in Order," Minneapolis, MN (January 13, 2011).
- Speaker, Elsevier, "510(k) Reform: Adapting to New FDA Standards and Changes," Webinar (January 12, 2011).
- Speaker, LifeScience Alley Conference and Expo 2010, "Using Social Media & Direct-to-Consumer Marketing in a Regulated Environment," Minneapolis, MN (December 8, 2010).
- Speaker, LifeScience Alley, "Commercializing New Technology, Begin with the End in Mind," St. Paul, MN (October 27, 2010).
- Panelist, Musculoskeletal New Ventures Conference," What's New With the 510(k) Program," Memphis, TN (October 18, 2010).
- Speaker, MetricStream/Compliance Online, "Using Social Media in a FDA Compliant Manner," Webinar, (October 20, 2010).
- Speaker, MedMarc/Compliance Online, "Social Media & FDA Regulations," Webinar (August 25, 2010).

- Speaker, Elsevier, "What the New 510(k) Will Mean for You," Webinar, (August 25, 2010).

- Speaker, University of Minnesota School of Journalism and LaBreche, "Social Media & FDA Regulations," Minneapolis, MN (July 24, 2010).

- Speaker, Medmarc, 23rd Annual Medical Device Seminar, "The 510(k) Program at FDA: Being Alice in Wonderland," Isle of Palms, South Carolina (June 6, 2010).

- Speaker/Panelist, LifeScience Alley, "Commercializing New Technology," St. Louis Park, Minnesota (June 2, 2010).

- Speaker, World Congress on "Minimally Invasive Spine Surgery," Las Vegas, Nevada (June 1, 2010).

- Speaker, Elsevier, "510(k) is Changing: What You Must Know to Obtain Clearance." Live National Audio Conference, United States (May 27, 2010).

- Speaker, Metric Stream/Compliance, "Fraud & Abuse in Healthcare Sales and Marketing – Update on the Law and Tips on Compliance," webinar (May 26, 2010).

- Interviewer/Speaker, IBF MedTech Investing Conference, "A Fireside Chat With Dan Schultz (about the 510(k) program)," Minneapolis, Minnesota (May 20, 2010).

- Speaker, VPanel (Shift Worldwide), "Can US MedTech Device Investing Survive the Health Care Reform Bill?" Live National Audio Conference, United States (May 6, 2010).

- Panelist, LifeScience Alley, "Fraud & Abuse, Enforcement & Compliance – Rules of the Road for Sales & Marketing," New Brighton, Minnesota (April 29, 2010).

- Speaker, VPanel (Shift Worldwide), "Is Regulatory Red Tape Hindering MedTech Investment?" National Audio Conference (April 22, 2010).

- Panelist, University of Minnesota, Design of Medical Devices Conference, "Panel Discussion: Upping the Ante, or, Is the Deck Stacked Against Medical Device Entrepreneurs?" Minneapolis, Minnesota (April 13, 2010).

- Speaker, MetricStream/Compliance Online Forum, "Appropriate and Lawful Off-Label Dissemination," Live National Audio Conference, United States (February 23, 2010).

- Speaker/Meeting Chair, Minnesota Medical Device Alliance, "A Call-to-Action: Make Your Voice Heard on the 510(k) Program," Minneapolis, Minnesota (February 17, 2010).

- Speaker, Medmarc Loss Control, "FDA Outlook For 2010," Live National Audio Conference, United States (February 10, 2010).

- Speaker, MetricStream/Compliance Online Forum, "Lawful Pre-FDA Approval & Pre-FDA Clearance Communication," Live National Audio Conference, United States (February 3, 2010).

- Speaker, LifeScience Alley, "Social Media in a Regulated Environment," St. Louis Park, Minnesota (January 28, 2010).

- Speaker, LifeScience Alley, "The 510(k) Program under Siege - Part II, What's Going on at the FDA?" St. Louis Park, Minnesota (November 19, 2009).

- Speaker, Thompson Audio Conference, "The De Novo Process: It's Growing Importance Post-ReGen," Live National Audio Conference, United States (November 18, 2009).

- Instructor, Hamline University School of Law, "Food & Drug Law, Practicing FDA Law," St. Paul, Minnesota (November 18, 2009).

- Speaker, 7th Annual MidAmerica Healthcare Venture Forum "The New Regulatory Paths & How BioSimilars are Affecting Reimbursement," Minneapolis, Minnesota (November 12, 2009).

- Instructor, "Masters in Regulatory Affairs Program, Combination Products Class," St. Cloud State University, Minneapolis, Minnesota (November 2, 2009).

- Speaker/Moderator, Orthopedic Surgical Manufacturers Association (OSMA) Meeting "510(k) Process Panel—Legal, Legislative and Industry Perspectives," (October 9, 2009).

- Speaker, Bowman & Brooke, "FDA Regulatory and Compliance Update," St. Louis Park, Minnesota (September 30, 2009).

- Speaker, Thompson Audio Conference, "Under Attack or on the Attack?: The 510(k) Program—Where it is Headed and What You Can Do About it Now?" Live National Audio Conference, United States (July 8, 2009).

- Speaker, IBF MedTech Investing Conference, "A Fireside Chat With FDA (about the 510(k) program)," Minneapolis, Minnesota (May 7, 2009).

- Speaker/Moderator, LifeScience Alley, "The 510(k) Program Under Siege: Part I," St. Louis Park, Minnesota (April 29, 2009).

- Instructor, "Masters in Regulatory Affairs Program, Combination Products Class," St. Cloud State University, St. Cloud, Minnesota (April 6, 2009).

- Speaker, LifeScience Alley, "Regulatory 101: Enforcement Administrative, Civil and Criminal," Minneapolis, Minnesota (March 11, 2009).

- Speaker, Thompson Audio Conference, "Is the FDA asking too much of your 510(k)?" Live National Audio Conference, United States (September 24, 2008).

- Moderator, FDLI, "Advertising and Promotion for the Pharmaceutical, Medical Device Biologics and Veterinary Medicine Industries," Medical Devices breakout session. Washington D.C. (September 8, 2008).

- Speaker, LifeScience Alley, "Avoiding Government Scrutiny in Reimbursement: The Kyphon Case and Beyond," Minneapolis, Minnesota (July 8, 2008).

- Speaker, LifeScience Alley, "Medical Device Commercialization: Getting Great Ideas to Market," Minneapolis, Minnesota (June 9, 2008).

- Speaker, IBF MedTech Investing Conference, "A Fireside Chat With FDA" (about the 510(k) program), Minneapolis, Minnesota (May 14, 2008).

- Speaker/Panelist, Regulatory Affairs Professional Society (RAPS), "Advertising, Promotion and Labeling Conference, FDA Regulatory Updates." Baltimore, Maryland (May 12, 2008).

- Speaker, LifeScience Alley, "Best Practices: Clinical Considerations for Studying/Communicating Off-Label Uses." St. Paul, Minnesota (May 8, 2008).

- Moderator, Oppenheimer MedTech Trends Seminar Series: "Speaking to the CEO's: A Real Insider's View to Reimbursement," Minneapolis, Minnesota (April 22, 2008).

- Speaker, Carlson School of Management and College of Pharmacy, "Executive Roundtable," Minneapolis, Minnesota (April 2, 2008).

- Moderator, FDLI & FDA Annual Conference, "New Technology Reports," Washington D.C. (March 26, 2008).

- Speaker, Creekridge Capital, Medtech CFO Breakfast "The Medtech Marketing & Regulatory Landscape," Minneapolis, Minnesota (March 14, 2008).

- Speaker, LifeScience Alley, "Regulatory Affairs 101 (Enforcement)," St. Louis Park, Minnesota (March 12, 2008).

- Speaker, "Masters in Regulatory Affairs Program, Reimbursement Class," St. Cloud State University. St. Cloud, Minnesota (March 10, 2008).

- Moderator, MedTech Resource Alliance, "How Virtual Are You? Virtual Companies & Outsourcing in MedTech," Minneapolis, Minnesota (February 28, 2008).

- Speaker, ePharmaceuticals Live Audioconference, "Post Launch: Aggressive, Compliant Marketing Strategies," United States (February 24, 2008).

- Speaker, HCPro National Webcast, "Device Compliance: Off-Label Sales Risk Areas," (December 20, 2007).

- Moderator, LifeScience Alley Annual Conference, "Next Generation Combination Products," St. Paul, Minnesota (December 7, 2007).

- Speaker, LifeScience Alley-Advertising and Promotion, "Back to School in Device Advertising," Minneapolis, Minnesota (October 24, 2007).

- Panelist, FDLI Advertising and Promotion Conference, "Breakout Session-Medical Devices," Washington D. C. (September 18, 2007).

- Speaker, LifeScience Alley, "Neuromodulation Program," Minneapolis, Minnesota, (June 5, 2007).

- Speaker, MedTech Investing Conference, "Management of Physician Involvement in MedTech Companies," Minneapolis, Minnesota, (May 16, 2007).

- Speaker, Regulatory Affairs Professionals Society (RAPS) Advertising, Promotion and Labeling Conference, "Beyond FDA: Other Government Enforcement Activities," Minneapolis, Minnesota (May 10, 2007).

- Speaker, University of Minnesota Carlson School of Business-College of Pharmacy, "Executive Roundtable," Minneapolis, Minnesota (May 2, 2007).

- Speaker, PharmaMed Device Conference, "Follow the Yellow Brick Road: The Path to Combination Product Approvals to (or through) OCP," New York, New York (April 25, 2007).

- Panelist, Healthcare Resource Connection (HRC), "FDA Dispute Resolution Process—First Hand Experiences," Minneapolis, Minnesota (April 18, 2007).

- Speaker, Association of Clinical Research Professionals (ACRP), Twin Cities Chapter, "Physician-Initiated Clinical Trials: Clinical Being the Lord of the Rings," Edina, Minnesota (April 12, 2007).

- Speaker, LifeScience Alley, "It Ain't Lake Wobegon Any More: Avoiding Mayhem in the Midwest in the Marketing of Your Products," St. Louis Park, Minnesota, (March 20, 2007).

- Panelist, Oppenheimer Wolff & Donnelly, LLP, MedTech Trends Seminar Series: "Work the Process: Clinical Trials & Reimbursement," Minneapolis, Minnesota (February 21, 2007).

- Speaker, HCPro, Inc., "Tracking Aggregate Spend: Compliance Pitfalls and Best Practices," Live National Audio Conference, United States (February 14, 2007).

- Speaker, Biomedical Focus Conference, "Regulatory Strategies for Making a Choice Between Class II & III Devices," panel, Minneapolis, Minnesota (February 13, 2007).

- Speaker, 4th Annual Pharmaceutical Marketing Compliance Conference, "Innovative Approaches to Compliance Training," panel, Washington D. C. (January 29, 2007).

- Speaker, Informa Life Sciences- Drug Device Combination Products, "Combination Products: Choosing What You Want To Be When You Grow Up," Brussels, Belgium, (November 20, 2006).

- Speaker, HCPro, Inc., "Pre-Approval Product Awareness: Compliant, Creative Activities and KOL Interaction," Live National Audio Conference, United States (October 10, 2006).

- Panelist, FDLI Advertising and Promotion Conference, "Breakout Session- Medical Devices," Washington D. C. (September 18, 2006).

- Speaker, Regulatory Affairs Professional Society, "Strategic Regulatory Planning," Minneapolis, Minnesota (August 17, 2006).

- Speaker, HCPro, Inc., "Medical Science Liaison Compliance: Real-World Scenarios & Perspectives," Live National Audio Conference, United States (June 7, 2006).

- Speaker, Medical Marketing Association National Conference, "FDA's Regulation of Pre-Approval Communications and Off-Label Information: Dorothy, You're Not in Kansas Anymore," Chicago, Illinois (June 1, 2006).

- Speaker, Manufacturers Alliance Association, "Balancing Competing Interests in Clinical Trial Enrollment," held at Boston Scientific, Maple Grove, Minnesota (May 3, 2006).

- Panelist, Harvard Club of MN, "Technology Panel-Biotechnology Question and Answers," Minneapolis, Minnesota (April 27, 2006).

- Speaker, LifeScience Alley (Formerly Medical Alley/MNBIO), "Physician-Initiated Research Issues," St. Louis Park, Minnesota (April 19, 2006).

- Speaker, Oppenheimer Wolff & Donnelly, LLP Breakfast Series, "MedTech Trends: Product Development and Marketing: Beginning With the End in Mind," St. Louis Park, Minnesota (April 12, 2006).

- Panelist, Food and Drug Law Institute (FDLI) 49th Annual Conference, "CDRH Panel with Center Director, Dr. Schultz," Washington, D.C. (April 7, 2006).

- Speaker, American Society of Quality, "Inspections, Recalls, and FDA Warning Letters," Bloomington, MN (March 14, 2006).

- Speaker, ePharmaceuticals Live Audioconference, "Post Launch: Aggressive, Compliant Marketing Strategies," United States (February 24, 2006).

- Moderator, Medical Alley, "The OIG & DoJ: Where Have They Been & Where Are They Going with Medical Device, Pharmaceutical and Health Care Provider Enforcement?" Minneapolis, MN (December 14, 2005).

- Speaker, MedTech Trends Seminar Series, "How to Push the Envelope in Promoting Medical Devices Without Pushing FDA's Hot Buttons," Minneapolis, MN (November 16, 2005).

- Speaker, CBI's Executive Summit on Forging the Way For Combination Products – The Convergence of Drugs, Devices and Biologics, "Strategically Select and Pursue a Regulatory Pathway for a Combination Product," Minneapolis, MN (October 24 – 25, 2005).

- Speaker, Medical Alley, "The World is a Stage: Will You Be Writing a Successful Script for Your Technology?" Minneapolis, MN (October 6, 2005).

- Speaker, HCCA Midwest Area Compliance Conference, "Compliance Program Developments for Pharma & Med Device Companies," Minneapolis, MN (September 16, 2005).

- Speaker, (SoCRA) Society of Clinical Research Associates, 14th Annual Conference, "Physician initiated clinical trials: Clinical Being 'The Lord of the Rings'," Orlando, FL (September 23 – 25 2005).

- Moderator, 4th Annual Medtech Investing Conference, "Post Marketing Clinical Trials: Will you Need Them?" panel, Minneapolis, MN, (May 11-12, 2005).

- Speaker, Minnesota State Bar Association (MSBA), Health Law Section, "Understanding and Influencing FDA," Minneapolis, MN (April 22, 2005).

- Speaker, Medical Alley seminar, "The Lord of the Rings (the temptation of the "Ring" of Reimbursement)," Minneapolis, MN (April 5, 2005).

- Speaker, Barnett International, Developing Combination Products Conference, "Combination Products: Choosing What You Want to be When You Grow Up," San Diego, CA (March 7 -8 2005).

- Speaker, Lifecycle Management for Pharmaceuticals, Extending the Life, Value & Profitability of Your Brand, "'Until Death Do Us Part:' Living Up to Your Product Vows Using LCM Strategies," Ft. Lauderdale, FL (Oct. 26, 2004).

- Panelist, Lifecycle Management for Pharmaceuticals, Extending the Life, Value & Profitability of Your Brand, "Ensuring Life After Launch: Converting Challenges into Opportunities," Ft. Lauderdale, FL (October 25, 2004).

- Split Rock Ventures 2004 Clinical Trial Summit, "Split Rock Partners' View of the Clinical Process and What Keeps Us Up At Night," Burlingame, CA (Oct. 21, 2004).

- Panelist, Pharmaceutical Marketing Congress, "Contrasting Marketing Challenges in Small, Medium and Large Pharma," Philadelphia, PA (Sept. 29, 2004).

- Speaker and Panelist, Pharmaceutical Marketing Congress, "Meeting Regulatory Requirements for Drug Marketing, Advertising and Promotion," Philadelphia, PA (Sept. 27, 2004).

- Speaker, Got Patients? Breakfast Series by Padilla Spear & Beardsley, "Driving Demand Through Patient-Focused Marketing--the Business and Regulatory Aspects of Direct-to-Patient Marketing," Minneapolis, MN (Sept. 21, 2004).

- Speaker, Food and Drug Law Institute (FDLI) Advanced Medical Devices Conference, "FDA's Regulation of Pre-approval Communications and Off-label Information: A Tornado is Swirling in Kansas," San Francisco, CA (June 23, 2004).

- Speaker, Medical Alley/Minnesota State Bar Association, "Peter Pan Meets Captain Hook: Will the OIG Help Peter Grow Up?" Minneapolis, MN. (May 19, 2004).

- Speaker, Regulatory Affairs Professional Society (RAPS) Advertising, Promotion and Labeling, "Fraud and Abuse: Watching Marketing Dollars Flow," Minneapolis, MN. (May 18, 2004).

- Speaker, University of Minnesota- Carlson School of Management, "Product Development—Beginning with the End in Mind," Minneapolis, MN (April 14, 2004).

- Speaker, Regulatory Affairs Professionals Society (RAPS), "Ethical and Regulatory Compliance for Device and Drug-Device Combination Trials," Minneapolis, MN (Mar. 11, 2004).

- Speaker, Medical Alley, "Advertising and Promotion of Medical Devices," Minneapolis, MN (Mar. 10, 2004).

- Speaker and Moderator, 8th Annual Drug Delivery Partnerships Conference, "Combination Products—Regulatory Challenges or Opportunities?" Beverly Hills, CA (Jan. 27, 2004).

- Speaker, Drug Delivery Partnerships Conference, "Life Cycle Management (LCM)- How to Get Your "Act" Together: A Perspective From a Former In-house Lawyer/Business Person," Minneapolis, MN (Jan. 28, 2004).

- Speaker, Medical Alley, "Combination Products: Choosing What You Want To Be When You Grow Up," Minneapolis, MN (Jan. 14, 2004).

- Speaker, Regulatory Affairs Professional Society (RAPS), "Welcome to the Hogwarts School of Marketing Wizardry—A Regulatory Affairs Professional Society (RAPS) Meeting," Baltimore, MD (Nov, 2003).

- Speaker, Medical Alley, "For Love of Research or Money? What You Should Consider in Supporting Physician-initiated Research," Minneapolis, MN (Aug. 2003).

- Speaker, Biomedical Focus 2003 seminar, "Peter Pan Meets Captain Hook: Will Quality Systems be able to help Peter grow up?" Bloomington, MN (Apr. 15, 2003).

- Speaker, Food and Drug Law Institute (FDLI) Advanced Medical Devices Conference, "FDA's Regulation of Pre-approval Communications and Off-label Information: A Tornado is Swirling in Kansas," Washington, D.C. (Feb. 12, 2003).

- Speaker, MedicalSuds seminar, "Beyond a Conventional View of Medical Trials," Minneapolis, MN (Jan. 30, 2003).

- Speaker, Medical Alley seminar, "FDA's Regulation of Pre-Approval Communications and Off-label Dissemination: A Tornado is Swirling in Kansas", Minneapolis, MN (Jan. 8, 2003).

- Speaker and moderator, (two panels), Drug Information Association (DIA) seminar, "Annual FDA Enforcement Update" (moderator)" and "FDA Regulation of Pre-approval Communications (speaker on 1st Amendment free commercial speech issues in WLF, Pearson v. Shalala and Western States cases)," Chicago, IL (June 18, 2002).

- Speaker and commentator (two panels), Food and Drug Law Institute, (FDLI) seminar, "Hatch-Waxman: Past, Present & Future," Washington, D.C., (Dec. 11 – 12, 2000) (chosen industry representative to debate FTC and FDA on intellectual property issues in the federal Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act).

- Speaker, Drug Information Association (DIA) seminar, "Promoting, Prescribing, and Paying for Off-Label Indications: Impact of FDAMA, The Washington Legal Foundation Case, and the Internet," Washington, D.C., (April 6 - 7, 2000).

- Commentator and co-chair, FDLI Seminar, "How to Promote Your Company's Products: A Marketing, Regulatory, and Medical Perspective," Chicago, IL (July 21-22, 1998).

- Commentator and co-chair of FDLI Seminar, "Marketing and Advertising Your Company's Products Legally and Effectively," Wash., D.C. (September 3, 1997).

- Speaker, DIA Seminar, "FDA Policy on Pharmacoeconomic Claims," Montreal, Canada (June 25, 1997) (debated Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, (CDER) FDA).

- Commentator, FDLI Seminar, "Marketing and Advertising of Drugs, Medical Devices, and Biologics in a New Environment," Washington, D.C. (September 7, 1995).

- Creator, co-chair and speaker at Food and Drug Law Institute Seminar "Strategic Planning for Crisis Management," Washington, D.C. (June 7, 1995).

- Speaker, FDLI Seminar, "Seminar on Anti-Kickback Issues," Washington, D.C. (March 3, 1995).

- Speaker, "Product Liability from a Manufacturer's Perspective," American Association of Homes and Services for the Aging, Orlando, FL, (November 8, 1994).

- Creator, co-chair and speaker at FDLI Seminar, "Strategic Planning for Crisis Management," Minneapolis, MN (June 6 & 7, 1994).

- Panelist, FDLI Seminar, "Advertising and Promotion," Washington, D.C. (September 14, 1992).

- Speaker, Pharmaceutical Research Manufacturers Association (PhRMA), Annual Marketing Executives Meeting, "Drug Advertising and Promotional Issues," Fort Lauderdale, FL (October 1991).

- Speaker, FDLI Seminar, "FDA Initiatives in Advertising & Promotion of Prescription Drugs," Washington, D.C. (September 6, 1991).

PUBLICATIONS

Author of Chapter 3 entitled "Regulatory," and advisor in the book "Inventor's Guide for Medical Technology From Your Napkin to the Market, What Innovators need to Know," 1st Edition (2011).

"Off-label Communications: A Guide to Sales and Marketing Compliance," Chapter 3 "Off-label Discussion Before and During Clinical Trials—Avoiding Off-Label Pitfalls," Edited by Mark Carlisle Levy, Published by FDLI (2009).

Chapter in "How to Work With the FDA: Tips From the Experts," Chapter 10 "Persuading the FDA to Your Position," 2nd Edition, Edited by Wayne Pines, Published by FDLI (2003).

Chapter in book "Communicating in a Health Care Crisis," chapters 1 and 2 entitled "Strategic Planning for Crisis Management," and "The Crisis Management Team," and a third chapter entitled "The Tambocor Crisis: Avoiding Our Own Heart Attack," Edited by Wayne Pines, FDA News (2007).

Chapter in "When Lightening Strikes—A How to Crisis Manual With Classic Case Studies," Chapters 2 and 3 "Strategic Planning for Crisis Management," and "The Crisis Management Team," Edited by Wayne Pines, Washington Business Information, Inc. (1994).

Article in FDLU's Update magazine: "Advertising and Promoting Dietary Supplements; How to Avoid Being Consumed by Government Prosecutors." (September-October 2011).

Article in FDLI's Update magazine, Food and Drug Law, Regulation and Education, "Off-Label Dissemination: What the Constitution Giveth, Are the OIG and DoJ Taking Away?" (January-February 2004).

Article in FDLI's Update magazine, Food and Drug Law, Regulation and Education, "The Prosecutorial Prism: Are We All Felons?" (March-April 2005).

Article for FDLI's Update magazine entitled "First Mickey Mouse, then the WLF Case and DTC Advertising – American Exports to the European Community" (about the effect of U.S. regulation and 1st Amendment free speech case law on promotion in Europe due to global impact of the Internet) (Jan. 2001).

Article in Star Tribune, "What Should We Do About Biotech?" (November 2003).

Article in Star Tribune, "The Art of the Possible" (May 2003).

"Defensive Drafting to Protect Intellectual Property Agreements," Faulkner & Gray's Bankruptcy Law Review, Vol. 2, No. 3 (Fall 1990) 21.

"How Do Intellectual Property Licensees Spell Relief? "IPLBA"," Faulkner & Gray's Bankruptcy Law Review, Vol. 2, No. 2 (Summer 1990) 5.

"When Everything Goes Wrong: Special Issues Pertaining to Technology as Part of a Bankruptcy Proceeding," Prepared for Seminar "TECHNOLOGY-BASED CONTRACTS" 1987, Minnesota Institute of Legal Education (January 16, 1987).
"Guarantees, Letters of Credit and Security Deposits in Bankruptcy," Prepared for The American Association of Equipment Lessors Lawyers' Forum (May 22-23, 1986), Chicago, Illinois.

"A Trial Lawyer's Perspective: What You Always Wanted to Know About RICO Before Your Case Was Dismissed," 12 William Mitchell Law Review 291 (1986).

"RICO's Congressional History and Future," prepared for Seminar: "Rico, Rico Everywhere!" Minnesota Institute of Legal Education (November 15, 1985).

"Recognition and Enforcement of Foreign Country Money-Judgments: To Be or Not To Be?" prepared for Seminar: "Business Opportunities In Europe During 1986" conducted by Larkin, Hoffman, Daly & Lindgren, Ltd., (November 21, 1985).

"Lost Profits for Lost Volume: A Businessperson's Pipe Dream or Entitlement?," 9 William Mitchell Law Review 266 (1983).